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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,235	08/10/2006	Callum Colquhoun	DEP5167USPCT	1326

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PHILIP S. JOHNSON  
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ONE JOHNSON & JOHNSON PLAZA  
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EXAMINER
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FERNANDEZ, KATHERINE L

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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07/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,235	<b>Applicant(s)</b> COLQUHOUN, CALLUM	
	<b>Examiner</b> KATHERINE L. FERNANDEZ	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 8-11 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2009 has been entered.

***Claim Objections***

2. Claims 16 and 19 are objected to because of the following informalities:

Claim 16 recites the limitation "and is configured be deflected" in line 2, which should be corrected to --- and is configured to be deflected ---.

Claim 19 recites the limitation "the third second limb" in line 4. There is insufficient antecedent basis for this limitation in the claim. Examiner assumes applicant meant "the third limb".

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1-4, 7 and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by White et al. (US Patent No. 6,656,184).

White et al. disclose a bone screw comprising: an anchor mechanism (12) configured to be attached to a bone; a support having a first end and a second end, the first end attached to the anchor mechanism (column 4, lines 34-41, wherein the support comprises at least one limb that is resiliently deformable (20,22) (i.e. helical spring with flat abutting surfaces (see element (20, 22), Figures 1-2, wherein the helical spring (22) is pictured with flat abutting surfaces))); and at least one reference member attached to the second end of the support, the at least one reference member configured to be detected by an image guided system to identify the location of the at least one reference member relative to the bone (i.e. the bone screw is made of material such as stainless steel, titanium, cobalt-chrome alloys, etc. which are known in the art to be detectable by image guided systems, such as optical/camera systems) (column 4, lines 14-18), wherein the support comprises at least one resiliently deformable limb (20,22) (i.e. helical spring with flat abutting surfaces (see element (20, 22), Figures 1-2)), such as but not limited to a single or double helix (column 4, lines 14-41), configured such that, when the anchor mechanism is attached to the bone, at least a portion of the at least one limb extends away from the bone (see Figures 4 and 5) (column 4, lines 14-55). The compressive member is allowed to return to its relaxed state after being stressed (column 6, lines 22-43). As can be seen in Figures 1-2, the ratio of the outer diameter of the compressive member (20) to its inner diameter is at most 3:1. The support further comprises at least one rigid limb (see Figure 3, the section between the

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compressive member (22) and the distal portion (12) and the section between the compressive member (22) and the head portion (16) are rigid limbs of the support).

5. Claims 1-3 and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Smothers et al. (US Pub No. 2003/0181918).

Smothers et al. disclose a bone marker for use in image guided surgery, comprising: an anchor mechanism configured to be attached to a bone (pg. 6, paragraphs [0065]-[0066], [0069]; see Figures 12 and 21); a support (52) having a first end and a second end, the first end attached to the anchor mechanism (pg. 6, paragraph [0066]); at least one reference member (12) attached to the second end of the support, the at least one reference member configured to be detected by an image guided system to identify the location of the at least one reference member relative to the bone (pg. 6, paragraph [0069], pg. 4, paragraph [0044], [0050]); wherein the support comprises at least one resiliently deformable limb (52) configured such that, when the anchor mechanism is attached to the bone, at least a portion of the at least one limb extends away from the bone (pg. 6, paragraphs [0065]-[0066]; see Figures 12 and 21). The support further comprises at least one rigid limb (pg. 6, paragraph [0068]). The resiliently deformable limb can comprise of a tightly wound helical spring (pg. 6, paragraph [0066]). The reference members can transmit or reflect signals (pg. 4, paragraph [0050]).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Nassar et al. (US Patent No. 5,389,107).

As discussed above, White et al. meet the limitations of claim 1. However, White et al. do not specifically disclose that the deformable limb is made from a damped elastomer. Nassar et al. disclose a shock absorbent prosthetic hip joint, which significantly dampens the force of impact caused by walking, running or similar activities (column 1, lines 8-10). They disclose that their shock absorbent hip joint can comprise of a volumetric spring that can comprise of a plurality of resilient spherical elements composed of a suitable elastomer (column 4, lines 44-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of White et al. to have the resiliently deformable limb be made from a damped elastomer, as Nassar et al. teaches the use of an elastomer as a resiliently deformable material.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Lieberman (US Patent No. 6,527,774).

As discussed above, White et al. meet the limitations of claim 1. However, they do not specifically disclose that the deformable limb is made from a shape memory alloy. Lieberman discloses an apparatus for attaching fractured sections of bone in a patient's body, and which prevents relative rotation of the fractured sections of bone

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without damaging the sections (column 1, lines 18-24). They disclose that their apparatus comprises a bone screw having a platform for drivingly rotating the bone screw and at least two helical spikes for embedding into at least one of the first and second sections of the bone upon rotation of the platform (column 2, lines 23-43). They disclose that the bone screw and the helical spikes can be made from a shape memory alloy, which has the ability to return to a predetermined shape (column 10, lines 34-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the deformable limb of White et al. be made from a shape memory alloy, as taught by Lieberman et al., as shape memory materials have the ability to return to a predetermined shape.

9. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Carson (US Pub No. 2002/0198451).

As discussed above, White et al. meet the limitations of claim 1. However, they do not specifically disclose that the reference members transmit signals or reflect signals. Carson discloses systems and processes for tracking anatomy, implements, instrumentation, trial implants, implant components and virtual constructs or references, and rendering images and data related to them in connection with orthopedic, surgical and other operations (pg. 1, paragraph [0002]). They disclose that such systems and processes allow more accurate and effective resection of bone, placement and assessment of trial implants and joint performance, and placement and assessment of performance of actual implants and joint performance (pg. 1, paragraph [0002]; pg. 2,

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paragraph [0012]). They disclose that their invention uses position and/or orientation tracking sensors such as infrared sensors to track the positions of body parts, surgery-related items such as implements, instrumentation, trail prosthetics, prosthetic components, etc (pgs 1-2, paragraph [0011]). They disclose that the position/orientation tracking sensors and fiducials can consist of reflective elements or can be any electromagnetic, electrostatic, light, sound, radiofrequency or other desired technique, such as an "active" fiducial (i.e. microchip, transponders) (pg. 4, paragraphs [0054]-[0055]). They further disclose that the fiducials can be implanted in the body parts or in any of the surgically related devices and may also take the form of conventional structures such as a screw driven into a bone (pg. 4, paragraph [0055]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention White et al. to have the reference members transmit signals or reflect signals, as taught by Carson, as fiducials that transmit or reflect signals and are attached to surgical items, such as a bone screw, can help a surgeon navigate the items more accurately, efficiently and with better alignment and stability during a surgical procedure (pg. 2, paragraph [0012], pg. 1, paragraph [0002]).

10. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smothers et al. as applied to claim 1.

As discussed above, Smothers et al. meet the limitations of claim 1. They further disclose that the flexible reducer (50) is capable of being even slightly flexed or bent, turned, bowed or twisted, without breaking (pg. 6, paragraph [0065]). It would have been obvious to one of ordinary skill in the art to have the at least one resiliently



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deformable limb have an axis and be configured to be deflected up to 90 degrees away from the axis before its elastic limit is exceeded and have the resiliently deformable limb have an axial length and an axis and configured to be deflected perpendicularly away from the axis by up to a distance of 70% of the axial length before its elastic limit is exceeded, as the resiliently deformable limb (50) is capable of being bent without breaking (pg. 6, paragraph [0065]).

### ***Allowable Subject Matter***

11. Claims 8-11 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or suggest a coupling member for coupling the support to a fixation member of the anchor mechanism of the bone marker, wherein the coupling member is adjustable to allow rotation of the support about the fixation member or that the support comprises a first limb, a second limb and a third limb, and the at least one reference member comprises a first reference member attached to the first limb, a second reference member attached to the second limb, and a third reference member attached to the third limb, in combination with the other claimed elements.

### ***Response to Arguments***

12. With regards to claims 1-7, 12-13 and 17-18, Applicant's arguments filed May 4, 2009 have been fully considered but they are not persuasive.

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Applicant argues that the compressive member (22) of White is not resilient, as it has been filled with a material that is permitted to harden, and therefore the limitation of the support comprising of "at least one resiliently deformable limb" is not met. However, the addition of the resorbable material does not change the compressive member itself, and thus the compressive member still comprises of a resiliently deformable material. It is further noted that White discloses that the resorbable material will gradually resorb, allowing the compressive member to relax (i.e. compressive material returns to its natural state, and therefore is made of resiliently deformable material) (column 6, lines 22-28). The mechanical properties of the compressive member, such as the ability of the material of the compressive member to resiliently deform, has not fundamentally changed, and therefore, structurally, the compressive member meets the limitation of the support comprising at least one resiliently deformable limb.

Applicant further argues that the bone screw of White is not configured to be detected by an image guided system. However, it is noted by the Examiner that no limitations are set forth on the image guided system itself, and therefore the image guided system can be any imaging device, such as an optical camera. As it is well known in the art that any physical object is detectable and imageable by an imaging device, such as an optical camera, the bone screw taught by White is structurally configured to be detected by an image guided system, thus allowing the location of the at least one reference member relative to the bone to be identified. As the claim does not set forth a specific manner by which reference markers are to be detected, the White reference still meets the above limitation. Examiner notes that claims directed to

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an apparatus must be distinguishable from the prior art in terms of structure rather than function.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768